EXHIBIT 1

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UNITED STA. _S DEPARTMENT OF COMMERCE Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, O.C. 20231

| SERIAL NUMBER FILING DATE FIRST NAMED IN | EVENTOR ATTORNEY DOCKET HO. |
|---|---|
| 07/413,395 09/27/89 GREENSPAN | 1 |
| | EXAMINER |
| TIMOTHY J. MARTIN | |
| 44 UNTON BLVD., STE. 620 LAKEWOOD, CO 80228 | SPEAR, J ART UNIT PAPER NUMBER |
| LAREWOOD, CO COLLS | 152 |
| | DATE MAILED: |
| This is a communication from the examiner in charge of your application | 06/18/90 |
| COMMISSIONER OF PATENTS AND TRADEMARKS | , |
| | |
| ETA | _ |
| This application has been examined Responsive to communication filed | |
| A shortened statutory period for response to this action is set to expire | month(s), days from the date of this letter. |
| Part THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION: | |
| 579 | |
| | Notice re Patent Drawing, PTO-948. Notice of Informal Patent Application, Form PTO-152 |
| 5. Information on How to Effect Drawing Changes, PTO-1474. | |
| Part II SUMMARY OF ACTION | |
| 1. 🗵 Claims | are pending in the application |
| Of the above, claims 6-18 | |
| 2. Claims | |
| | are allowed. |
| ************************************** | Dewood are also also |
| • | are rejected. |
| 5. Cleims | |
| 6. Claims | |
| 7. This application has been filed with informal drawings under 37 C.F.Fl. 1. | .85 which are acceptable for examination purposes. |
| Formal drawings are required in response to this Office action. | |
| The corrected or substitute drawings have been received on are acceptable: not acceptable (see explanation or Notice re Pa) | . Under 37 C.F.R. 1.84 these drawings |
| 10. The proposed additional or substitute sheet(s) of drawings, filed on | |
| examiner: disapproved by the examiner (see explanation). | . has (nave) been L1 approved by the |
| 11. The proposed drawing correction, filed has been | an 🔲 approved; 🗋 disapproved (see explanation). |
| 12. Acknowledgement is made of the claim for priority under U.S.C. 119. The | a cartified crow has IT been received. IT not have married |
| Since this application apppears to be in condition for allowance except for accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 C | of formal matters, prosequiton as in the monte is closed in |
| 14. Other | , |
| | |

EXAMINER'S ACTION

PTOL-326 (Rev.9-89)

-2-

Art Unit 152

This action is in response to the election with traverse of claims 1-15 submitted May 17, 1990 by Timothy J. Martin. The applicants' arguments have beam considered but they are not deemed to be persuasive.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claim 1 is rejected under 35 U.S.C. 103 as being unpatentable over Coleman, The Citrus Industry Pub:, November 1975.

Coleman shows a lotion hand cleaner comprising approximately 57% d-limonene, moisturizer (lanolin) and emulsifying agents (Arlacel and Tween). Although distilled citrus oil (94% d-limonene) is used it would be obvious to use orange oil, if it were not the source in this case. Page 24-25.

Claim 2 is rejected under 35 U.S.C. 103 as being

Serial No. 413,395

Art Unit 152

-3-

unpatentable over Coleman as applied to claim 1 above, and further in view of Dellutri US 4,620,937.

Dellutri shows a skin cleaner comprising d-limonene and further comprising aloe vera. To use aloe vera in the Coleman invention would be obvious since both inventors teach hand cleaners of similar compositions containing moisturizers. Col. 1, lines 60-65. Col. 3, lines 23-28.

Claims 3-7; 9-15 are rejected under 35 U.S.C. 103 as being unpatentable over Coleman and Dellutri as applied to claim 2 above, and further in view of Juliano et al US 4,014,995.

Juliano for claim 3 shows compositions for use on the skin containing oat flour. Juliano further shows oat flour as an emulsifier. Col. 1, lines 34-40. Col. 3, lines 16-25. To use the oat flour in the invention described above would be obvious in as much as the use of emulsifiers is a well recognized art. Nothing unobvious is seen by using oatmeal in claim 4, since oatmeal by definition is ground oats of a larger particle size than flour.

For claim 5 both Dellutri and Juliano teach compositions having a ph of 5.5. Juliano col. 2, lines 3-13, col. 3, lines 5-15. Dellurti col. 3, lines 52-59.

Serial No. 413,395 Art Unit 152

-4-

For claims 6-7 Juliano teaches the inclusion of substances to maintain a specific ph. Nothing un-obvious is seen in applicant' use of a ph range of 4.5-6, since the prior art shows the importance of ph balanced preparations for on the skinuse.

Claim 8 is rejected under 35 U.S.C. 103 as being unpatentable over Coleman, Dellutri, Juliano as applied to claims 1-7 above, and further in view of Jones US 4,5 33,487.

Jones shows the preparation of d-limonene containing buffers. The preparation is rendered harmless to the skin primarily due to the presence of the buffersSum,Col. 3, lines 43-50. To use the buffered stable d-limonene preparations of Jones in the above mentioned inventions would be obvious in view of the prior art teachings. Note Dellutri's use of stabilized d-limonenė. Col. 2, lines 19-23.

For claims 9-11 see Coleman, Dellutril and Juliano as applied to claim 3 above.

For claim 12 see Juliano as applied to claim 4 above.

For claims 13-15 see Coleman and Dellutri as applied to claim 2. Glycerin, aloe vera, jojoba oil and safflower oil are considered equivalents. Nothing un-obvious is seen in applicants use of mixtures.

Serial No. 413,395

Art Unit 152

-5-

Hewell Cladus ?

The motivation to produce cleaning compositions for use on the skin arises from the teachings of Coleman, Dellutri, Juliano and Jones who suggest the desirability to prepare cleaners comprised of orange oil having enhanced cleaning properties. The formulations are non-toxic, stable and non irritating to the skin. Claims 145 are rejected.

The Group and/or Art Unit location of your application in the Patent and Trademark Office has changed. . To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 150, Art Unit 152.

Any inquiry concerning this communication should be directed to James M. Spear at telephone number 703-557-6525.

Spear:pla

(703) 557-6525

06/11/90

TO SEPARATE, HIT! TOP AND BOTTOM EDGES, SNAP-APART AND DIFF OD CARBON

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|-----------------------|--|-----------------------|-------------|----------|--------|------|---|------------|-------|-------------------------------------|---|-----------------|--|-------------|-------------|-------------------------------|----|
| | NOTICE OF REFERENCES CITED Greenspan etal. | | | | | | | | | | | | | | | | |
| U.S. PATENT DOCUMENTS | | | | | | | | | | | | | | | | | |
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| 5 | a | M | e | <u>ڪ</u> | 11 | 1, 5 | F | e | ar 6 | - 1-91 | | | | | | | |
| | * A copy of this reference is not being furnished with this office action. (See Manual of Patent Examining Procedure, section 707.05 (a).) | | | | | | | | | | | | | | | | |

EXHIBIT 2

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SE: 2/ 1990

152

GROUP 150 IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

atent Application for

Freenspan and Low Mal No.: 07/413,395 led: September 27, 1989

Filed: September 27, 1989
For: CLEANING COMPOSITIONS WITH
ORANGE OIL

Date: September 18, 1990

Group: Art Unit 152 Examiner: J. Spear Action: AMENDMENT

5C

TO: The Commissioner of Patents and Trademark Office Washington, DC 20231

Sir:

In response to the Office Action of 18 June 1990, please reconsider the claims of this application in view of the following remarks:

REMARKS

These remarks are in response to the Office Action of 18 June 1990 in the above referenced patent application. In that application, Claims 1-18 were pending. However, Claims 16-18 were deemed withdrawn from consideration despite Applicants' traverse of the election.

Of the remaining claims, Claim 1 was rejected over Coleman, The Citrus Industry Publication, November 1975 under 35 U.S.C. Section 103. Claim 2 was rejected over Coleman in further view of U.S. Patent No. 4,620,937 to Dellutri under 35 U.S.C. Section 103. Claims 3-7 and 9-15 were rejected over Coleman and Dellutri in further view of U.S. 4,014,995 to Juliano. Claim 8 was rejected over the Coleman reference in view of Dellutri and Juliano and in further view of U.S. Patent No. 4,553,487 to Jones.

At the outset, Applicants note with appreciation the thoroughness of the Examiner's comments in applying the cited references against the claims. However, Applicants have not amended their claims since they believe that the references teach away from the present invention, as currently claimed, so that all of the claims in this application are allowable over these references. Applicants' position is supported by two arguments.

First, as the Examiner has noted, none of the cited references disclose the use of orange oil as a primary constituent. Rather, each of the references rely on the cleaning properties of d-limonene as the primary cleaning constituent. The Examiner then concludes that it would be obvious to substitute orange oil for the d-limonene since the d-limonene is distilled from a citrus oil.

Simply put, these references do not suggest the use of orange oil alone, but rather teach away from the use of orange oil since they rely on the distillate d-limonene. Applicants have found that undistilled orange oil has higher cleaning properties when used in a composition than distilled d-limonene. Applicants have tested the compositions produced according to the ranges of the present application wherein an equal weight percent of d-limonene was substituted for the orange oil. In each case, the orange oil based composition had superior cleaning properties than the identical composition with an equivalent amount of d-limonene substituted for the orange oil. While Applicants believe that other esters and volatiles in the orange oil may contribute to the enhanced cleaning properties, although the

exact reason for the enhanced cleaning properties has not yet been determined. Nonetheless, Applicants have learned of a surprising result from the raw orange oil in these enhanced cleaning properties. This distinction over the use of d-limonene in the prior art is significant and not at all obvious. Indeed, Applicants have found that their composition is effective on substances such as wrethane caulking, paint and tar that resist d-limonene cleaning compositions.

The enhanced cleaning property of orange oil contributes to the second distinction between the compositions recited in this application and the prior art. A review of the prior art shows that d-limonene is used in weight percentage ratios that are above the lower ratios claimed in the present application. These ratios run from a low of 51% d-limonene (Coleman) to a high of approximately 70% d-limonene (Coleman). Dellutri uses approximately 58%-60% d-limonene. As noted in the Coleman reference, citrus oil contains approximately 94% d-limonene so that the equivalent amount of citrus oil necessary to provide the amount of d-limonene in the prior art compositions run from approximately 55%-75%.

Claim 1 of the present application claims a range of 5% to 60% orange oil which, as noted above, allows for greater cleaning ability for lesser of the included cleaning agent (orange oil): Since the expense of orange oil is fairly substantial, this surprising result allows a reduction in the proportion of orange oil as opposed to d-limonene, and this leads to substantial economies.

A derivative benefit is seen where the quantity of orange oil, (and thus the amount of d-limonene) since studies have indicated that d-limonene may have carcinogenic effects. For example, the attached study taken from the National Toxicology Study Program (January 1990) indicates a possible adverse effect from excess d-limonene. Where a cleaning composition is intended as one suitable for hand cleaning, as is the present invention, the benefits from reducing the quantity of d-limonene while maintaining the cleaning ability may be appreciated without further explanation.

Accordingly, all of the claims in this application are believed allowable for the inclusion of orange oil. However, several points directed to the dependent claims are in order since it is believed that the dependent claims contain allowable subject matter in their own right. In particular, those claims including the use of oat-grain derivatives and oatmeal. Here, it has been found that the oatmeal may lend cleaning properties in that oatmeal acts as a drawing agent to help remove certain oils or other materials from the surface to be cleaned. It also adds an abrasive quality to the cleaning compound to enhance the scrubbing ability.

Based on the foregoing, it is believed that this application is conditioned for allowance and action to that end is courteously solicited. Should the Examiner request any further information, in the form of affidavits or otherwise, regarding the matters addressed in this Amendment, the Examiner is invited to contact attorney for the Applicants at the telephone number

Applicants would specifically listed below. opportunity to submit such affidavits in the event that the Examiner maintains the rejection of the present application.

Respectfully submitted,

TIMOTHY J. MARTIN, P.C.

Timothy J. Mar. 1, #28,64 Dana Rewoldt, #P-33,762 44 Union Blvd., Suite 620 #28,640 4 Lakewood, Colorado (303) 988-0800 80228

CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.8

I hereby certify that the foregoing AMENDMENT is being deposited with the United States Postal Service as first-class mail, postage prepaid, in an envelope addressed to The Commissioner of Patents and Trademarks, Washington, DC 20231, on this day of September, 1990.

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NTP TECHNICAL REPORT

ON THE

TOXICOLOGY AND CARCINOGENESIS STUDIES OF d-LIMONENE

(CAS NO. 5989-27-5)

IN F344/N RATS AND B6C3F1 MICE

(GAVAGE STUDIES)

C.W. Jameson, Ph.D., Study Scientist

NATIONAL TOXICOLOGY PROGRAM P.O. Box 12233 Research Triangle Park, NC 27709

January 1990

NTP TR 347

NIH Publication No. 90-2802

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service National Institutes of Health

EXHIBIT 3

Conclusions: Under the conditions of these 2-year gavage studies, there was clear evidence of carcinogenic activity* of d-limonene for male F344/N rats, as shown by increased incidences of tubular cell hyperplasia, adenomas, and adenocarcinomas of the kidney. There was no evidence of carcinogenic activity of d-limonene for female F344/N rats that received 300 or 600 mg/kg. There was no evidence of carcinogenic activity of d-limonene for male B8C3F₁ mice that received 250 or 500 mg/kg. There was no evidence of carcinogenic activity of d-limonene for female B6C3F1 mice that received 500 or

An increased severity of spontaneous nephropathy, increased incidences of linear mineralization of the renal medulla and papilla, and hyperplasis of the transitional epithelium of the renal papilla were present in dosed male rats.

SUMMARY OF THE TWO-YEAR GAVAGE AND GENETIC TOXICOLOGY STUDIES OF &LIMONENE

| Male F344/N Rate | Female F344/N Rats | Male B6C3F _t Mice | Female B6C3F; Mice |
|--|---|---|---|
| Doses 0,75, or 150 mg/kg d-limosens in corn oil by gavage, 5 d/wk | 0, 300, or 600 mg/kg d-limonene in corn oil by gavage, 5 d/wk | 0, 250, or 500 mg/kg d-limanene in corn oil by gavage, 5 d/wk | 0, 500, or 1,000 mg/kg d-limonene in corn oil by gavage, 5 d/wk |
| Body weights in the 2-year Approximately 5% reduction in high does group | study Approximately 5% reduction in high dose group | Na effect | 10% reduction in high dos group by end of study |
| Survival rates in the S-year 29/50; 33/50; 40/50 | r study 42/50; 40/50; 26/60 | 33/50; 24/50; 39/50 | 43/50; 44/50; 43/50 |
| Nonneoplastic effects Mineralization (7/50; 43/50; 48/50) and spithelial hyper- plasis (0/50; 25/50; 45/50) of the renal papilla; renal tuhtular cali hyperplasia (0/50; 4/50; 7/50) | None | None - | None |
| Neoplastic effects Renal tubular cell adeno- mas (0/50; 4/50; 8/50) and adenocarcinomas (0/50; 4/50; 3/50) | None | None | None |
| Level of evidence of carcin Clear evidence | sogenic activity No evidence | No evidence | No evidence |
| Genetic toxicology assays 5. typhisurium (gene metalion) Negative with and without 88 | Mouse L5178Y/TK*/- (Tit-resistance) Negative with and without 59 | SCB Negative with and without 89 | Its in Vitro Abstration Negative with and without 69 |

^{*}Explanation of Levels of Evidence of Carcinogenic Artivity is on page 8. A summary of the Feer Review comments and the public discussion on this Technical Report appears on pages 9-10.



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| . TIMOTHY J. | MADTIN | | | SPEAR, J | |
| 44 UNION B | LVD., STE. | 520 | • | ART UNIT | PAPER NUMBER |
| LAKEWOOD, | CO 80228 | · | | 152 | 6 |
| | | | | DATE MARLED: | |
| This is a communication from COMMISSIONER OF PATER | s the examiner is charge of NTS AND TRADEMARKS | your application, | | | 12/20/90 |
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| This application has bee | n exemined | sponsive to communical | ion filed on | V | This motion is made final. |
| shortened statutory period | | | 3man#h(*), | tieye from | he date of this letter. |
| erti nidhir broqees of esufe | - | • • • | | d. 35 U.S.C. 123 | • |
| HI THE FOLLOWING | ATTACHMENT(8) ARE | PART OF THE ACTIC | M: | | |
| 1. Notice of Referen | | | | re Petent Drawing, Pi | |
| | nd by Applicant, PTO-1- our to Effect Drewing C | | 4. Notice | of Informal Patient Ap | pilostion, Form PTO-182 |
| et # SUMMARY OF AC | TION | - | | | |
| | . 15 | | | | |
| 1. Claims | | · · · · · · · · · · · · · · · · · · · | | · · · · · · · · · · · · · · · · · · · | are pending in the application |
| Of the abo | ove, claims | | | | withdrawn from consideratio |
| 2 Claims | | | | | have been cancelled. |
| 2. Claims | | | | | are allowed. |
| 4. De Claims | 2, 5-9 | and 1 | L | | are rejected. |
| s. Acleime 3 | -4,10 | and 1 | 2-15 | | are objected to, |
| e. Claims | 7 | | | ing subject to residuals | n or election requirement. |
| 7. This application is | as been that with infor | mel drawings (swiss 47) | | | • |
| 8. Formal drawings | | | and an interpolational sec | | seconds for frame. |
| <u></u> | | | | | |
| 8. The corrected or acceptab | oje: 🔲 uoj accebiepje Amerikas cismančia jas | ve been received on (see explanation or Not | os re Patent Drawing | , PTO-948). | \$7 G.F.R. 1,84 these drawin |
| 10. The proposed ac | iditional or substitute at | heat(s) of drawings, Hed | on | has (have) been | 2 approved by the |
| examiner; () di | sapproved by the exam | iner (see explanation). | | | • |
| 11. The proposed des | | | | | |
| 12. Adknowledgemen | nt is made of the claim (parent application, serie | or priority under U.B.C. | 119. The certified o | opy has 🏻 been rece | hed D not been received. |
| 13. Since this applica | tion apppears to be in o | oondition for allowance s erie Queyle, 1855 G.D. | mospi for formal mai 11:455 O.G. ±13. | ters, prosecution as to | the merits is closed in |
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| 14. Other | | | | | |
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| 14.□ Other | | | | | |

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Serial No. 413,395

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Art Unit 152

15.

Applicant's arguments filed September 18, 1990 have been fully considered but they are not deemed to be persuasive.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-2, 9 and 11 are rejected under 35 U.S.C. § 103 as being unpatentable over Dellutri US 4,620,937.

For claim 1, Dellutri shows compositions wherein 20-90% citric oil is used in combination with stearic acid, oleic acid and aloe vera. See col. 2, lines 10-13, Claims 1 and 7. Note that the stearic and oleic acids emulsify the composition. Col. 2, lines 33-38. Aloe Vera acts as a moisturizer as in applicants' claimed invention. Col. 3, lines 23-28. Dellutri

Serial No. 413,395 Art Unit 152

-3-

does not specify orange oil. IT would have been obvious to one of ordinary skill in the art to the use orange oil the motivation factor being suggested by Dellutri's use of undistilled citrus oil. Although distilled D-Limonene is preferred, Dellutri teaches that citrus oil, which can be derived from oranges, is suitable for the invention. Col. 2, lines 10-17, thus negating applicants' claim of unobviousness.

For claims 2, 9 and 11, see Dellutri as explained above. 18.

Claims 5-8 are rejected under 35 U.S.C. § 103 as being unpatentable over Dellutri as applied to claim 1 above, and further in view of Juliano US 4,014,995.

Juliano teaches the inclusion of substances to maintain a specific pH. Both Juliano and Dellutri teach compositions having teach compositions having a pH of 5.5 Juliano col. 2, lines 3-13, col. 3, lines 5-15. Dellutri col. 3, lines 52-59. To use Juliano's agent in the Dellutri invention would have been obvious to one of ordinary skill in the art. The motivation to do so is suggested by Dellutri's use of emulsifiers in view of Juliano's teaching emulsifiers in maintaining pH.

Claims 1-2, 5-9 and 11 are rejected.

19.

Claims 3-4, 10 and 12-15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten

Serial No. 413,395

Art Unit 152

in independent form including all of the limitations of the base claim and any intervening claims.

20.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 152.

-5-

Serial No. 413,395 Art Unit 152

22.

Any inquiry concerning this communication should be directed to James M. Spear at telephone number (703) 308-2457.

Spear: 1td December 18, 1990 (703) 308-2351

EXHIBIT 4

IN THE I TED STATES PATENT AND TRAFFMARK OFFICE

RE: Patent Application for Douglas Greenspan et al Serial No.: 07/786,804
Filed: November 4, 1991
For: CITRUS OIL COMPOSITIONS AND USES THEREOF

Date: June 15, 1997
Art Unit: 1500
Examiner: R. Bawa
Action: AMENDMENT

TO: The Commissioner of Patents and Trademarks Washington, DC 20231

Sir:

In response the Decision by the Board of Patent Appeals and Interferences mailed April 15, 1997, Applicant elects to further prosecute this case before the Primary Examiner and requests that the application be amended as follows:

In the claims:

1. A method of externally treating human skin including the steps of:

applying to said skin a composition having a first ingredient being between five percent (5%) and sixty percent (60%) by volume of orange oil, a second ingredient being a pharmaceutically acceptable moisturizer for human skin [including] containing a plant material [such as plant oils and plant extract] and a third ingredient being an emulsifying agent in the form of a grain based derivative.

- 15. A method according to claim 1 wherein said composition is [operative] adapted when applied to human skin which is sunburned to reduce the peeling of the human skin resulting from said sunburn.
- 16. A method according to claim 1 wherein said composition is [operative] adapted when applied to human skin to repel insects from human tissue.

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Case 1:04-cv-01507-SLR

- 17. A method for treating acne on human skin comprising the step of applying a composition including fortn-five percent (45%) or less by volume of orange oil, forty-five percent (45%) or less by volume of a grain based emulsifying agent in the form of a grain based derivative, and a pharmaceutically acceptable moisturizer including plant material [such as] selected from a group consisting of plant oils and plant extract to said acme on the human skin.
- 18. A [composition] method according to claim 17 wherein said emulsifying agent is oatmeal.
- 19. A [composition] method according to claim 17 wherein said moisturizer is a mixture of jojoba oil, aloe vera and glycerine.
- A [composition] method according to claim [17] 19 20. wherein said mixture includes by volume four parts jojoba oil, five parts aloe vera and two parts glycerin.
- A [composition] method according to claim [17] 19 wherein said mixture includes safflower oil.
- 25. A cleaning product comprising a towellet formed of an absorbent material, said towellet being impregnated with a cleaning composition and hermetically sealed in a packet member wherein said cleaning composition comprises a first ingredient being between five percent (5%) and sixty percent (60%) by volume of orange oil, a second ingredient being a pharmaceutically acceptable moisturizer for human skin including a plant material [such as] selected from a group consisting of plant oils and plant extract[, for human skin] and a third ingredient being a grain based emulsifying agent in the form of an oat grain based

derivative pror at.

Kindly add the following claim:

26. A method according to claim 1 wherein said plant material is selected from a group consisting of: plant oils and plant extracts.

Remarks

The present Amendment is in response to the Decision by the Board of Patent of Appeals and Interferences and is submitted in accordance with 37 C.F.R. \$1.196(b)(1) for consideration by the Primary Examiner.

In its decision, the Board noted that the Examiner has not, to date, relied upon any prior art in rejecting the claims on appeal. With respect to the Examiner's rejections of claims 1-3, 5-21 and 25 under 35 U.S.C. \$112(a), this has been reversed by the Board. The Board has, however, affirmed the rejection of these claims under 35 U.S.C. \$112(b). In addition, the Board has entered new grounds of rejection pursuant to 37 C.F.R. \$1.196(b) as well as raised various issues requiring the Examiner's attention. This response is specifically directed to these new grounds of rejection.

With respect to the new grounds of rejection, the Board has rejected claims 1-3, 5-21 and 25 under 35 U.S.C. \$112(b) as being indefinite. Specifically, the Board maintains that the use of the phrase "such as" in claims 1, 17 and 25 raises the question as whether plant oils and plant extracts are exemplary or limiting. In response to this, an amendment is made to each of claims 17 and 25 to now recite, without being limiting, a plant material is selected from a group consisting of plant oils and

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plant extract : .. It is believed that "e exemplary wording adequately addresses the Board's concerns under \$112(b). Claim 1 has been amended to reflect that the second ingredient contains a plant material.

A new claim 26 has been added to include the deleted language from claim 1 that the plant material is either a plant oil or a plant extract. This claim makes a positive recitation No additional fling fee is believed of this limitation. necessary for this added claim, however, due to previous cancellation of claims for which the full filing fee was paid. The Commissioner is hereby authorized to charge any deficiency in the payment of the required fee(s) or credit any overpayment to Deposit Account No. 13-1940.

The Board also maintains that the scope of claims 15 and 16 is unclear in that there is no indication what, if anything, needs to be done so that the composition is "operative" for the stated purposes. In an effort to address these concerns of the Board, Appellant has amended claims 15 and 16 tea now recite that the composition is adapted to perform the stated purposes when Again, Appellant respectfully applied to the human skin. disagrees with the Board that the recitation "operative" is unclear by necessarily requiring that something actually be done to the composition in order for it to effectuate these results. Notwithstanding this, the word adapted is incorporated to remove any such perceived unclarity. That is, when the composition having the ingredients recited in claim 1 is applied to the skin, it is adapted to both reduce skin peeling and repel insects. Only application of the composition to human skin is required for

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these things to happen.

The Board has correctly pointed out that claims 17-21 are indefinite and that claim 17 is directed to a method for treating acne on human skin while claims 18-21 are directed to compositions. Upon review of the previous amendments filed in this case, it appears that this inadvertent mistake arose as a result of an amendment filed on February 9, 1993. communication, claim 17 was amended to recite a method as opposed to a composition; however, Applicant inadvertently neglected to amend claims 18-21 accordingly. Therefore, the Examiner will please note that each of claims 18-19 has now been amended to recite a method, with claims 20 and 21 also amended to properly recite their dependence from dependent claim 19. amendments fully address the Board's concerns and do not add any new matter to this application.

Claims 1, 2, 5-17 and 19-21 are rejected under 35 U.S.C. \$112(a) as being non-enabled by the supporting specification. The Board deems certain statements made in the specification as an admission that the weed based derivatives recited in claims 1 and 17 are not useful as an emulsifying agent. The Examiner will please note that on May 15, 1997, Appellant submitted a request for modification of this portion of the Board's decision, maintaining that no such admissions of any kind were made. The Board has yet to render its decision on such request for modification. Accordingly, it is believed that a substantive response to the Board's enablement rejection, articulated on page 8 of its decision on appeal, is premature until such decision is Nonetheless, a copy of Appellant's request for rendered.

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modification (decision on appeal is ttached hereto and incorporated herein by reference.

Finally, the Board has entered two new rejections of some of the claims over the prior art. Specifically, claims 1-3 and 5-18 are rejected under 35 U.S.C. §103 as being obvious over the combination of Coleman, Dellutri and FDR 1969. Claim 25 is rejected as being obvious under 35 U.S.C. \$103 over the combination above and further in view of PDR 1989. With respect to the first of these rejections, the Board briefly summarizes the respective teachings of Coleman, Dellutri and PDR 1969 and then maintains that the hypothetical person having knowledge of these references would have found it obvious to use the claimed composition to treat damaged skin.

While Appellant does not disagree with the respective teachings of the references, it is submitted that one of ordinary skill in this field would not be motivated to arrive at the claimed combination based on these teachings alone. With respect to each of independent claims 1, 17 and 25 a composition is required which broadly contains three ingredients - orange oil, a pharmaceutically acceptable moisturizer and an emulsifying agent in the form of a grain based derivative. The closest reference is Dellutri which describes a cleaning agent in the form of a hand cleaner which includes de-limonene obtained from orange oil and may also include, as an optional ingredient, aloe vera extract. Individually, Coleman describes the use of delimonene obtained from citrus oils, such as orange oil, as a hand cleaner. Individually, PDR 1969 shows that colloidal oatmeal may be used to treat various skin conditions. There is nothing in

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the prior art, 'wever, to suggest that one would be inclined to utilize oatmeal in a hand cleaner that may or may not include aloe vera extract. Dellutri is specifically directed to a nontoxic cleaning agent which can provide heavy duty industrial cleaning, yet which is mild enough to prevent irritation of the user's skir. Column 1, lines 30-33. Accordingly, Dellutri is in no way concerned with a composition for externally treating human skin which has been damaged. As such, and notwithstanding the teachings of PDR 1969 and PDR 1989, there would be no reason At most, one of ordinary skill to combine these teachings. having knowledge of Coleman and Dellutri would look to other sources of art for additives that might enhance the cleansing properties of a hand cleaning agent. One having knowledge of Dellutri would also look to other art for cleansers which are particularly useful in industrial cleaning applications. The FDR 1969 and PDR 1989 references, on the other hand, are more particularly directed to damaged skin, not unclean hands. Accordingly, it is suggested that any such combination of the prior art as suggested by the Board would be arbitrary because Coleman/Dellutri are actually directed to addressing different needs than the PDR references. At most, Coleman/Dellutri teach compositions which may be applied to human skin but do not teach compositions which are directed to alleviating or treating skin which has been damaged.

Notwithstanding the above, it is anticipated that the Examiner will need to conduct a new prior art search based on the Board's recommendations and its decision. Moreover, there are no outstanding rejections to date of claims 19-21. Therefore,

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while Appellar disagrees with the Boar 's determination of obviousness based on the new grounds of rejection, Appellant should be entitled to more fully address this issue after the Examiner has re-searched and re-evaluated the patentability of the pending claims in this application. It is also believed that any subsequent action by the Examiner in this regard should not be made final as it would necessarily contain new grounds of rejection.

Based on the foregoing, it is respectfully requested that the Examiner conduct a new prior art search based on the Board's It is also respectfully recommendations and its decision. requested that with the Board's determination of obviousness based on the new grounds of rejection, Appellant should be entitled to more fully address this issue after the Examiner has re-searched and re-evaluated the patentability of the pending It is also believed that any claims in this application. subsequent action by the Examiner in this regard should not be made final as it would necessarily contain new grounds of If any issues remain to be resolved prior to the rejection. granting of this application, it is requested that the Examiner contact the undersigned attorney for the Appellant.

> Respectfully submitted, TIMOTHY J. MARTIN, P.C.

Timothy J. Martin, #28,640 9250 W. 5th Avenue, Suite 200 Lakewood, Colorado 80226

(303) 232-3388

NGT, 3,1997 12:07PM TIMOTHY MARTIN PC

ETØ ON P.11

CERT CATE OF MAILING UNDER 37 F.R. 1.8

I hereby certify that the attached AMENDMENT INCLUDING COPY OF REQUEST FOR MODIFICATION OF DECISION ON APPEAL is being deposited with the United States Postal Service as first-class mail in an envelope addressed to the Assistant Commissioner of Patents Office, Washington, DC 20231, on this product of June, 1987.

MGT. 3.1997 12:87PM TIMOTHY MARTIN PC

EXHIBIT 5



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PRODUCT INFORMATION MASSENGILL®

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MASSENGILL® Powder INGREDIENTS

DISPOSABLES: Extra Mild Vinegue and Water Water and

Product Information

NIGHEDIENTS

DISPOSABLES: Eura Mild Vinegar and Water—Water and Vinegar.

Erts Cleaning Vinegar and Water—Water, Vinegar, Puracteral McCrypyridinatus Chloridel, Diamblidinyl Urea, Diamblidinyl Urea (Lein Marchall Diamblidinyl Urea (Lein Add) Schimm Lactate, Chicaynol-9, Cetylgyridiniam Chloride, Propylene Glycol Isand Diamblidinyl Urea (Lein Add) Schimm Lactate, Chicaynol-9, Cetylgyridiniam Chloride, Propylene Glycol Isand Diamblidinyl Urea (Lein Add) Schimm Lactate, Chicaynol-9, Cetylgyridiniam Chloride, Propylene Glycol Isand Diamblidinyl Urea (Lein Add) Schimp Lein Lein Add, Schim Blanthoush, Octaynol-9, Pragnanc, Ddd Yellow 210, FDdC Yellow 256 Sunset Yellow), Propylene Glycol Blanthoush, Octaynol-9, Pragnanc, Ddd Yellow 210, FDdC Yellow 256 Sunset Yellow), Propylene Glycol Blanthoush, Octaynol-9, Pragnanc, Ddd Yellow 210, FDdC Yellow 256 Sunset Yellow), Propylene Glycol Blanthoush, Octaynol-9, Sh Jarobel 20-A, Pragnance, and FDdC Yellow 266 Sunset Yellow).

RDDCATIONS

INDICATIONS

RESULTABLISTS

Recommended for routine eleganing at the end of menatrus-tion, after use of contraceptive creams or jellies (check the contraceptive package instructions first or to risme out the contraceptive package instructions first or to risme out the residue of prescribed vaginal medication (as directed by phy-

ACTIONS

The hoffered and solutions of Massengill Douches are valuable adjuncts to specific variant therapy following the practice are of variant medication or contraceptives and in feminine bygictee.

feminise bypicne.
DHECTIONS
DESPOSABLES: Twist off flat, wing-shaped tab from bottle containing premired solution, ettech notele supplied and nea. The tuit is completely disposable.

14000 CONCENTRATE: Fill cap % full, to measuring line, and pour contents into desurbe lag containing I quart of warm water. Mix thoroughly.

POWDER: Dissolve two rounded teaspoonfuls in a douche lag containing I quart of warm water. Mix thoroughly, and the supplied of the suppli

WARNING
Vaginal riessaing douches abould not be used more than brice weakly except on the advice of a physician. If irritation account, discontinue use, Keep out of reach of children. In case of accidental inpution, seek professional assistance by contacting your physician, the local poison curried center, or contacting your physician, the local poison curried center, or entering the physician, the local poison curried center, at Rocky MI. Prison Coursel Center at 200-829-1710 (Collect), 24 hours a day.

HOW SUPPLIED

NOW NOTTLEED Disposable—6 on disposable pinsie botile Liquid Concentrate—4 on 8 m. planic botiles Powder—4 on 8 on 16 m. 22 m. Packettes—10's, 12's

MASSENGILL® Medicand [may say gil] Disposable Douche MASSENGILL® Medicand

ACTIVE INGREDIENT
DISPOSABLE Ception (posidone indine)
LIQUID CONCENTRATE Ception (posidone) INDICATIONS

INDICATIONS

Per symptomatic relief of minor irritation and itching associated with variatin due to Candida albicans, Trichomouse vaginalis, and Gardnerella vaginalis.

ACTION

Sering pregnancy unless directed by a physi-

Tager & Water and Connetic Dooches -if irridistrict me.

Women with indinesensitivity

"In product, if symptoms persist after seven Pavidone-indice is widely recognized as an effective broad apactrum unicrohicide against bulk gram negative and gram positive besteria, fongi, yessts and pronoue. While remain-ing active in the presents of blood, serum or bodily secre-

WARNINGS

WARNINGS
If symptoms persist after seven days of use, or if redness, seedling or pain develop during treatment, council a physician. Woman with iodine-sensitivity should not use this product. Women may douche during mentrantion if they douche genity. Do not douche during mentrantion if they douche genity. Do not douche during pregnancy or while narring unless directed by a physician. Bouching does not previous pregnancy. Keep out of reach of children, in case of accidental ingration, seek professional assistance by northering software physician, the local prison control center, or the Bocky Mt. Poison Control Center at 300-592-1710 (Collect), 24 hours a day.

655

DOSAGE AND ADMINISTRATION

DOGAGE AND ADMINISTRATION

DISPONANCE: Dougs is provided as a single unit concentrate to be added to 6 on of santitiond water supplied in a disposable bottle. A specially designed needs is provided. After use, the unit is discarded. Use one bottle a day. Although symptoms may be relieved earlier, for maximum relief, use

the, too door one the relieved earlier, for maximum reason, use for seven days.

LIQUID CONCENTRATE— Four one capital into desiche bag contaming one quart of water. Mix theroughly, Use soon daily. Although symptoms nely be raileved earlier, for maximum valled, use for sown days.

HOW SUPPLIED HOW HUPPLIED
Dispossible—S on bottle of sanitimed water with 0.37 on, vial
of portifions begins and north.
Liquid Concentrate—4 on, 8 on, plastic bottles.

MASSENGILL® Medicated [mas*sen-gil] Soft Cleath Townleas

active ingredient Hydrocortisons (0.5%)

For southing relief of minor external feminine teching or other itching associated with minor attin irritations, inflam-mation, and rathes.

ACTION

AUALUM Messengili Medicated Soft Cloth Towelettes contain hydro-cortiones, a proven anti-inflammatory, anti-practic ingredi-ent. The toweletts delivery system makes the application sorting, soft, and gentle.

WARNING

WARNING

For external use only. Avoid contact with syrs, if condition

worsens, symptoms persist for more than seven days, or

symptoms recur within a few days, discontinuo use and consuit a physician. If experiencing a vaginal discharge, see a

physician.

Keep this and all drups out of the reach of chibren. As with

any drug, if pregnant or numing a buby, seek the advice of a

beauth profussional before using this product, in case of ac
dental ingradien, seek profusional sentance or contact a

Poison Control Center immediately.

DIRECTIONS

DIRECTIONS
Adults and Children two years of age and elder—apply to the
affected area not more than three to four times daily. Childran under two years of age—countl a physician before uning. Remove tweeletts from foll packet, gualty wine, and
discard. Throw away toweletts after it has been used once,

HOW SUPPLIED

Ten individually wrapped, disposable townlettes per earto

EDUCATIONAL MATERIAL

Booklet:
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A 16 page illustrated booklet on vaginal infections, feminine
hypiene and douching. Free to physicians, pharmacists and
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The 16 minutes color film begins with a simple explanation of how a weman's hody works insprinted by system, menstrual how a weman's hody works insprinted by the call and the cycle, and viginal secreticals then explains doubling. Free local to physicians, pharmaciers and clinks. Available in

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